

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : David S. Young et al.  
INVENTION : CANCEROUS DISEASE MODIFYING  
ANTIBODIES  
SERIAL NUMBER : 10/810,163  
FILING DATE : March 26, 2004  
EXAMINER : Susan Ungar  
GROUP ART UNIT : 1642  
OUR FILE NO. : 2056. 029

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**DECLARATION PURSUANT TO 37 CFR 1.132**

COMES now David S. Young, and avers the following:

I, David S. Young, do hereby declare as follows:

1. I am Chairman, President and CEO of Arius Research, Inc.
2. I am a co-inventor in United States Patent 7,256,272 (the '272 patent), issued August 14, 2007, which was filed on Nov. 13, 2003, as well as the instant application, which is a continuation-in-part of the '272 patent.
3. The Common Assignee in both applications is Arius Research Incorporated.

4. I have been given to understand that in the most recent action received from the USPTO, the Examiner has set a priority date of March 26, 2004 for the invention instantly claimed in the 10/820,263 application (the instant application), which is embodied by claims 21-28, which are drawn to the following:

Claim 21. The isolated monoclonal antibody produced by the hybridoma deposited with the ATCC as Accession Number PTA-5690.

Claim 22. A humanized antibody of the isolated monoclonal antibody of claim 21.

Claim 23. A chimeric antibody of the isolated monoclonal antibody of claim 21.

Claim 24. Antigen binding fragments of the isolated monoclonal antibody of claim 21.

Claim 25. Antigen binding fragments of the humanized antibody of claim 22.

Claim 26. Antigen binding fragments of the chimeric antibody of claim 23.

Claim 27.) The isolated antibody or antigen binding fragments of any one of claims 21, 22, 23, 24, 25 or 26 conjugated with a member selected from the group consisting of cytotoxic moieties,

enzymes, radioactive compounds, and hematogenous cells;

whereby antibody conjugates are formed.

Claim 28. The isolated hybridoma deposited with the ATCC as Accession Number PTA-5690.

6. I have further been given to understand that the Examiner has stated that the reasons for setting the priority date of March 26, 2004 is that a review of the parent application (the '272 patent) reveals that the Mab 5LAC-23 mentioned in the '272 patent is not the same antibody as the Mab 5LAC-23 mentioned in the instant application, this conclusion being arrived at for the reasons stated in paragraph 5 of the Office action mailed on April 4, 2007.

7. The Mab 5LAC-23 mentioned in the instant application is, in fact, the same as the Mab 5LAC-23 mentioned in the '272 patent, which Mab was deposited with the American Type Culture Collection, on December 9, 2003, under Accession Number PTA-5690 (copy attached hereto).

8. That the two sets of data relied upon by the Examiner in arriving at her conclusion, do not, in fact, contradict each other.

9. That there are key differences between the two data sets that the Examiner has not appreciated. The first set of data reported (in the '272 patent) was derived from screening data on cell culture supernatants (i.e. unpurified Ab); and the second

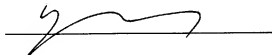
set of data, in the instant application, was derived from purified Ab.

10. That the first set of binding data was obtained by ELISA; the second by FACS. In an ELISA experiment data is traditionally reported as a ratio to isotype control; a ratio of less than 1 means that there is, in fact, no significant binding. Thus, in the '272 patent, the data actually shows that the Mab does NOT bind to NCI-H460 or CCD-27sk cells at all; there is no data reported for SW620 cells. Therefore, there is no contradiction here.

11. That for the cytotoxicity data, experimental protocols were different for these experiments, and cannot be readily correlated (again, an issue is that the '272 patent disclosure is on unpurified Mab, while the instant application is carried out second on purified Mab). Further, the numbers reported in the '272 patent are very low (8% and 5%), whereas in the instant application data is reported in a more subjective manner (i.e. using a +, ++ or +++ designation), and a level of 5 or 8% would have been considered not significant.

FURTHER, declarant sayeth not.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under 17 U. S. C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

A handwritten signature in black ink, appearing to be 'D. Young', is written over a horizontal line.

Dr. David S. Young

# ATCC

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## BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

### INTERNATIONAL FORM

#### RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.

To: (Name and Address of Depositor or Attorney)

Arius Research Inc.  
Attn: Valerie Harris  
55 York Street, 16<sup>th</sup> Floor  
Toronto, ON M5J 1R7  
CANADA

Deposited on Behalf of: Arius Research Inc.

Identification Reference by Depositor:

Patent Deposit Designation

Mouse hybridoma cell line: 5LAC-23  
Mouse hybridoma cell line: 6BD-25

PTA-5690  
PTA-5691

The deposits were accompanied by:    a scientific description, a proposed taxonomic description indicated above. The deposits were received December 9, 2003 by this International Depository Authority and have been accepted.

AT YOUR REQUEST:   X   We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested December 16, 2003. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

  
Marie Harris, Patent Specialist, ATCC Patent Depository

Date: December 23, 2003

cc: Mr. Ferris Lander

Ref: Docket or Case No.: 2056.009, 2056.026